JUN 3 0 2004

K041686

SMDA Summary— Special 510(k) Modified Product Labeling

Submitted by:
Arizant Healthcare Inc.
10393 West 70th Street
Eden Prairie, MN 55344
Telephone: 952-947-1200

Contact person:
David Westlin
Senior Director, Regulatory Affairs and Quality Assurance

Summary date:
June 21, 2004

Device name/trade name:
Bair Hugger Temperature Management System

Common/usual name:
Hyper/Hypothermia System

Classification name:
System, Thermal, Regulating, DWJ

Equivalent marketed device:
Bair Hugger temperature management system (K021473, K001149, K960167, K903360, K873745).

Device description:
The Bair Hugger temperature management system consists of a portable forced-air temperature management unit (series 500 or 700 units) and a disposable Bair Hugger forced-air blanket (various models).

Intended use of the device
The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Technological characteristics
The technological characteristics of the cleared devices do not change with this modification to product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Arizant Healthcare Inc.
c/o Mr. David Westlin
Senior Director, Regulatory Affairs and Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K041686
Bair Hugger Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulatory System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: June 21, 2004
Received: June 22, 2004

Dear Mr. Westlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041686

Device Name: Bair Hugger® Temperature Management System

The Bair Hugger temperature management system consists of a portable forced-air temperature management unit (series 500 or 700) and a disposable Bair Hugger forced-air blanket (various models).

Indications For Use:

The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

ision Sign-Off)
sion of Cardiovascular Devices

510(k) Number K041686